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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,828	11/30/2000	Fabien Schweighoffer	50146/004002	9055
21559	7590	12/03/2003	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			SIEW, JEFFREY	
			ART UNIT	PAPER NUMBER

1637

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/623,828	SCHWEIGHOFFER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey Siew	1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 09 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 58-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 60-103 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,251,590 in view of Chee et al (US 5,837,832 Nov. 17, 1998).

Claims 60-103 are drawn to product arrays of nucleic acids to exon or introns or exon-exon, intron intron junction in which the nucleic acids are formed by hybridizing RNA from a sample wherein in at least sequence is partially known with cDNA from a second sample and identifying from hybrids the unpaired regions from differential splicing.

Claims 1-25 to specific sequences on biological chips.

Chee et al teach oligonucleotide probes for detecting sequences that are identical to or different from specific reference sequence (see whole document esp. abstract). They teach probes to CFTR 10 exon (see Figure 7).

One of ordinary skill in the art would have been motivated to combine the array technology of Chee et al with the method of claims of US6,251,590 in order to identify the multiple nucleic acid sequences that exhibited differential splicing. It would have been prima facie obvious to apply nucleic acids of unpaired regions in Chee et al's array for high throughput capture and detection.

The response filed 9/9/03 states that a terminal disclaimer will be filed upon finding of allowable subject matter. At this time no such finding has been made, the double patenting rejections are maintained. It is noted that claim 93 was omitted by typographical error. The office would like to thank the response for noting the inadvertent omission.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Product claims 58-71 are drawn to nucleic acids that correspond to differential splicing. The product claims 72-90 are drawn to nucleic acids which retain or spliced in cell treated reference material. Claims 91-93 are drawn to nucleic acids that hybridize to spliced sequences. Claims 94-103 are drawn to method of immobilizing on solid

support. The specification discloses methods of obtaining nucleic acids that corresponded to spliced regions. The product claims however recite a broad and widely varying genus, the examiner must evaluate any necessary common attributes or features. Although the specification has a working example Grb2 gene spliced forms, the specification proposes to discover other members of the genus by using the qualitative screening method. There is no description of all the possible varying spliced exon, introns and junctions. The general knowledge in the art concerning spliced variants does not provide any indication of how the structure of one spliced variant within a single gene would be representative across all genes in all organisms. The nature of spliced genes is that they are variant structures and the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. The mere recitation of exon, intron or junctions of spliced variants is not provide the requisite level of description. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only minimal number of this genus is not representative of the variants of the genus and is sufficient to support the claim.

The response states that transplicing was well known to the skilled artisan, further that they performed a key word search coming up with 6,519 references and cites M.P.E.P section 2164(a). They also extensively cite the prior art. However, this section refers to enablement rejection. The basis of the 112 first paragraph rejection is written description. Moreover, as no references of the 6,519 set been provided, the evidence of a number of references that have the keyword is not found convincing. It is unclear as to what the references teach or do not teach. As for the prior art, the response states that Famigleietti et al, Raben et al and Le Fur show that one **could** select for differentially spliced nucleic acids. However, the argument is drawn to the

**enablement issue** rather than the **written description**. The lack of support lies within the specification. Moreover, the references each are drawn to single species of different genes and would not provide support for the broad coverage of the claims.

Second, the response state requirement that applicants call out each and every nucleic acid molecule to each and every junction of a gene is unreasonable. The standard does not require a calling out of every single species. However, it does require a sufficient number of species within such a broad genus. While it is agreed that every single species is not required, the specification does not provide a sufficient description of number of species to provide support for the broad genus claim, particularly when the genus contains a wide ranging and varying species.

Third, the response states that specification teaches products comprising such nucleic acids as presently claimed. The response cites specification in providing methods to generate such spliced regions. Again this is drawn to the enablement issue, the rejection is based on the lack of written description. The method does not provide support that applicant had in possession of the broad genus encompassed in the claims. The rejections are maintained.

### SUMMARY

3. No claims allowed.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### **CONCLUSION**

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

  
JEFFREY SIEW  
PRIMARY EXAMINER

November 29, 2003